UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Johns v. CR Bard et al.,
Case No. 2:18-cv-1509

MOTIONS IN LIMINE OPINION AND ORDER NO. 12

Before the Court is Defendants' Motion in Limine No. 15 to Exclude Evidence and Argument Concerning Marketing Materials and Acts of Defendants' Sales Representatives Not Relied Upon by the Prescribing Physician. (ECF No. 218.) For the reasons that follow, the motion is **GRANTED IN PART AND DENIED IN PART**.

I. Background[1]

This case is the first bellwether trial, selected from thousands of cases in this multidistrict litigation ("MDL"), alleging "that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1 (S. D. Ohio Sept. 1, 2020). This includes the Ventralight ST, the device implanted in Plaintiff. The Ventralight ST is a prescription medical device used for hernia repairs. The Food and Drug Administration ("FDA") cleared it for use through the premarket notification

[1] The Court assumes that the parties and other interested readers are familiar with the history of this case. For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order, *In re Davol, Inc., Polypropylene Hernia Mesh Prods. Liability Litigation*, Nos. 2:18-md-2486, 2:18-cv-01509, 2020 WL 5223363, at *1–6 (S. D. Ohio Sept. 1, 2020).

510(k) process in 2010 and later cleared it for use with the Echo Positioning System in 2011. The Ventralight ST is a multicomponent device made of a mesh that consists of polypropylene, polyglycolic acid fibers, and a bioresorbable hydrogel coating called "Sepra Technology" ("ST"). The ST-coated side of the mesh is placed against organs, such as the bowels, while the uncoated polypropylene side is placed against the fascia because the uncoated side maximizes tissue attachment, thus supporting the hernia repair. *Id.* at *1–2.

Plaintiff brings this action to recover for injuries sustained as a result of the implantation of Defendants' allegedly defective Ventralight ST device. *Id.* at *4. The crux of Plaintiff's claims is that the ST coating on the Ventralight ST resorbs too quickly. *Id.* at *13. This leads to the premature exposure of bare polypropylene to internal organs and tissues, increasing the risk of potential complications. Plaintiff alleges that this occurrence led to omental adhesions after his laparoscopic hernia repair surgery in 2015. Plaintiff asserts that Defendants knew that polypropylene is unsuitable for permanent implantation in the human body. *Id.* at *2–4. The following claims remain for trial: design defect, under negligence and strict liability theories; failure to warn, under negligence and strict liability theories; breach of express warranty; breach of implied warranty; breach of implied warranty of merchantability; negligent misrepresentation; and punitive damages. *Id.* at *6–25. Now, various evidentiary motions are ripe for adjudication.

Defendants filed their Motion in Limine No. 15, arguing that evidence of and arguments about "marketing materials and acts of Bard's sales representatives not relied on by Plaintiff or his implanting surgeon, Dr. Joseph Jensen" are inadmissible. (ECF No. 218 at PageID #11978.) The parties disagree about the scope of Defendants' motion, requiring multiple rounds of briefing to at least specify the type of evidence included in "marketing materials." (*E.g.*, ECF No. 360 at PageID #18820–21.) Defendants have raised various evidentiary objections in response to Plaintiff's

production of exhibits (*e.g.*, ECF No. 374), as well as the general objection that Plaintiff's production is not responsive to the subject of Defendants' motion—marketing materials (ECF No. 373 at PageID #20228). Oral argument on the motion was held. (ECF No. 437 at PageID #22650–62.) The motion is now ripe for adjudication.

II. Legal Standards and Governing Law

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975) ("A better practice is to deal with questions of admissibility of evidence as they arise."). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (quoting *Ind. Ins. Co*., 326 F. Supp. 2d at 846). The denial, in whole or in part, of a motion in limine does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion

outside of the trial context. *Ind. Ins. Co.*, 326 F. Supp. 2d at 846. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002).

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Irrelevant evidence is inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

III. Analysis

Defendants argue that evidence of and arguments about "marketing materials and acts of Bard's sales representatives not relied on by Plaintiff or his implanting surgeon, Dr. Joseph Jensen" are inadmissible because they are irrelevant under Federal Rules of Evidence 401 and 402 and unduly prejudicial under Federal Rule of Evidence 403. (ECF No. 218 at PageID #11978–79.) Before addressing the evidentiary issues raised by this motion, it is necessary to explain how the body of evidence implicated by this motion has grown during multiple rounds of briefing.

Initially, Defendants did not define marketing materials or attach any examples of the marketing materials they seek to exclude. Plaintiff responded broadly, attaching exhibits including deposition testimony, internal documents and PowerPoint presentations, regulatory documents, and public-facing marketing materials. (ECF No. 297-1 to 297-21.) Due to confusion about whether these attachments were exhibits Plaintiff sought to introduce at trial or exhibits simply supporting his arguments, the Court ordered Plaintiff to produce examples of the marketing

materials he intended to introduce at trial. (ECF No. 360 at PageID #18820–21.) Subsequently, Plaintiff produced forty-four exhibits. (ECF Nos. 368-1 to 368-44.) The Court ordered Plaintiff to categorize his exhibits to assist the Court in assessing their admissibility, which Plaintiff accomplished by designating six categories, as discussed *infra*, Part III.

Defendants' overriding contention throughout the briefing on this motion has been that Plaintiff has not produced responsive documents, *i.e.* marketing materials, which they later defined as "promotional and meant for doctors to consider in the decision-making process of how to treat their individual patients" (ECF No. 373 at PageID #20228), including "brochures, advertisements, items of that nature" (ECF No. 433 at PageID #22588). But the reality of the situation is that the exhibits are before the Court with at least some briefing.[2] And during oral argument, Defendants enlarged the scope of their motion in response to the breadth of the briefing and number of Plaintiff's exhibits, asking that the Court issue "an order excluding those documents and providing some guidance and guardrails." (ECF No. 437 at PageID #22652.) Accordingly, the Court endeavors to address the relevance and potential prejudice of each of the forty-four examples that Plaintiff organized by category to ensure the most efficient and expedient trial.

Two final housekeeping matters. First, Plaintiff attached Exhibit ECF No. 368-37, but did not include this exhibit in his categorization. Accordingly, the Court will not address this exhibit. Second, Defendants raise a variety of evidentiary objections under Federal Rules of Evidence 801–804, 702–703, 901, and 1006. (ECF No. 374 at PageID #20317, 20320; ECF No. 433-1.) These objections are necessarily brief given the format of the charts created by the parties to classify the exhibits. And importantly, Plaintiff has not had an opportunity to respond to these evidentiary

[2] For this reason, the Court declines to follow Plaintiff's approach, which is to not exclude the exhibits that Defendants argue are unresponsive. (ECF No. 434 at PageID #22621.) Plaintiff put these exhibits on the chopping block by producing them and briefing their admissibility in response to Defendants' motion.

objections. Given this context, the Court declines to address these issues without the benefit of more detailed argumentation from both sides. These objections are noted for the record.

A. Category 1: Non-marketing documents

Category one includes "[n]on-marketing documents provided for background and/or context." (ECF No. 431 at 22573.) Plaintiff does not indicate whether he intends to offer these documents at trial. (*See* ECF No. 431-1 at PageID #22577.) The Court assumes that Plaintiff will offer these exhibits at trial. By Plaintiff's own characterization, these exhibits are irrelevant to whether Dr. Jensen or Plaintiff knew and relied on Defendants' representations regarding the Ventralight ST. The remaining questions are whether these documents are relevant to other legal issues in this case and whether they do not unduly prejudice Defendants. Most of the documents are relevant to other issues and do not unduly prejudice Defendants.

First, Defendants' internal "RACA Checklist," which addresses the "regulatory and clinical strategy determination" for the Ventralight ST. (ECF No. 368-10 at PageID #19047.) This document sets out Defendants' strategy for gaining approval in the United States via the 510(k) premarket notification process. (*Id.* at PageID #19048.) The portion of the document that pertains to the United States regulatory strategy is relevant in this case because it informs Defendants' conduct in the approval process, which permitted the implantation of the device in Plaintiff, and is not prejudicial because it is part of the story of the Ventralight ST. *Old Chief v. United States*, 519 U.S. 172, 189 (1997); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6603657, at *8 (S.D. Ohio Oct. 20, 2020). The checklist details information such as Defendants' plan for biocompatibility testing, design verification testing, etc. (ECF No. 368-10 at PageID #19052.) However, the portion of the

document that pertains to other countries is irrelevant because Defendants' conduct in this case did not occur outside of this country.

Second, a draft of an audit by the British Standards Institution ("BSI") from May 2018 of Defendants' Sepramesh IP and Ventralight ST clinical data. (ECF No. 368-11 at PageID #19068.) This exhibit is relevant because it informs the reasonableness of Defendants' conduct while designing and marketing the Ventralight ST. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2020 WL 6440261, at *11–12 (S.D. Ohio Nov. 3, 2020) (permitting admission of part of the BSI audit). Particularly relevant is that BSI suggests Defendants' clinical testing did not generate sufficient data, which Defendants rejected. (ECF No. 368-11 at PageID #19074.) Because Sepramesh IP is a predicate device to the Ventralight ST (ECF No. 368-10 at PageID #19051; ECF No. 373 at PageID #20236), the Sepramesh IP portion of the audit is also relevant to whether Defendants satisfied the standard of care. At this time, there does not appear to be any risk of undue prejudice.

Next, two versions of a 2004 report completed by Genzyme comparing the performance of Sepramesh II (another name for Sepramesh IP) to Bard Mesh and Bard Composix E/X. (ECF Nos. 368-17 and 368-18.) The report indicated that there was no evidence of the Sepramesh hydrogel coating in animal subjects twenty-one and twenty-eight days after surgical implantation. (*E.g.*, ECF No. 368-17 at PageID #19151.) The connection between Defendants' Ventralight ST and this report, which was completed before Defendants acquired the technology for ST hydrogel coating from Genzyme, is that Sepramesh IP is a 510(k) predicate device to the Ventralight ST. This report is relevant because it shows that Defendants should have discovered this data from Genzyme when it acquired Genzyme's ST hydrogel technology. (ECF No. 368 at PageID

#18942.) Arguably, this data would have put Defendants on notice that the ST hydrogel coating did not last as long as Defendants marketed.[3] The probative value outweighs any unfair prejudice.

Moving on to a group of internal documents and accompanying emails that reference Defendants' animal study comparing the Ventralight ST to competitor devices. (ECF Nos. 368-30, -31, -32, -33, -34, -36.) Plaintiff offers this evidence to show that Defendants drove the Ventralight ST study for marketing and sales purposes, as opposed to pursuing independent scientific results that could have been more indicative of safety. (ECF No. 368 at PageID #18949.) This use of evidence attacks Defendants' reliance on their study, which they claim demonstrates that the Ventralight ST is safe and that they performed adequate testing. For instance, one email accompanying an attached internal presentation states that Defendants' study does not have "the ideal study design to scientifically understand [the Ventralight ST and the device it is compared to] over time, yet would probably help to move the ball down the field for Sales/Marketing." (ECF No. 368-31 at PageID #19618.)

The attachments to these emails, though relevant, contain needlessly cumulative information because each attachment addresses the animal study. Plaintiff does not show that these attachments serve a non-cumulative purpose. This trial will put heavy demands on the jury in terms of understanding the scientific, regulatory, and medical evidence, and unnecessarily duplicative evidence will confuse the juror and unreasonably add to the length of this trial. Plaintiff is permitted to tell his story at trial, but should part of these exhibits become too repetitive, Rule 403 requires excluding some of these exhibits.

[3] Defendants argue that this study does not address resorption rates of the hydrogel coating (ECF No. 433-1 at PageID #22606–08), but this does not mean the study is irrelevant. Plaintiff's claim is that the ST hydrogel coating lasts fewer than twenty-eight days and that Defendants knew or should have known so but continued to market the device as if the ST coating lasted twenty-eight days. This is sufficient to establish relevance.

Defendants offer two counterarguments. First, and more generally, Defendants argue that these emails and PowerPoint presentations are irrelevant because they address defects and complications not at issue in this case, specifically contracture and histological responses. (ECF No. 374 at PageID #20324.) The portions of the exhibits that address adhesions, Plaintiff's injury in this case, are certainly relevant. (*See, e.g.*, ECF No. 368-34 at PageID #19695.) The portions that address contracture and histological responses that are related to Plaintiff's theory that polypropylene oxidatively degrades and causes adhesions, these presentations are also relevant. *See* 2020 WL 6605542 at *19–21. If some histological responses are unconnected to Plaintiff's theory of injury, then only those parts of the exhibits are irrelevant.

Second, and more specifically, Defendants contend that the email accompanying an attachment (ECF No. 368-34) is irrelevant because it mentions a device, Physiomesh, from a competitor, Ethicon, as well as an abstract of an unrelated study about the Physiomesh device. (ECF No. 374 at PageID #20325.) The email frames Defendants' study and the unrelated study as a "one-two punch" against Ethicon. This email is relevant to the extent that it shows that Defendants molded the study to serve marketing purposes. Moreover, the purpose of the study was to assess the performance of Defendants' Ventralight ST and SorbaFix against Ethicon's Physiomesh and Securestrap devices. (ECF No. 368-34 at PageID #19691.) Comparisons between the Ventralight ST and other devices that address the performance of the ST coating are relevant, as is the amount of background on the other devices that will enable the jury to make sense of those comparisons.

Finally, the Court declines to address Exhibit P.1.1742, which Plaintiff listed in this category. (ECF No. 431-1 at PageID #22581). The Court cannot review the exhibit because it is was not attached to any of the briefing associated with Defendants' motion in limine.

B. Category 2: Evidence of molding the market and influencing standard of care

The next category is "[e]vidence relating to Defendants' 'molding the market' and/or influencing the 'medical standard of care.'" (ECF No. 431-1 at 22595.) The exhibits that Plaintiff identifies in this category are mostly emails with internal PowerPoint presentations attached (ECF Nos. 368-23, -25, -27, -28, -38, -39), as well as Defendants' published animal study (ECF No. 368-35), a speech for an internal sales meeting (ECF No. 368-26), and an email with an attached PowerPoint presentation for a National Hernia Society East meeting (ECF No. 368-40). As Defendants argue, none of these exhibits is a marketing material nor are they relevant to whether Dr. Jensen was adequately warned by Defendants about the risks posed by the Ventralight ST. (*E.g.*, ECF No. 433-1 at PageID #22595.) Most of these exhibits are relevant to the overall story that Plaintiff seeks to tell at trial and not unduly prejudicial, one exhibit is relevant to whether Defendants violated the applicable standard of care, and none are admissible to demonstrate that Defendants influenced the medical standard of care.

The majority of these exhibits are relevant to the broader theory of Plaintiff's case. Plaintiff argues that this category of evidence shows that Defendants molded the hernia mesh market, driving surgeons to their product in pursuit of financial goals. (*E.g.*, ECF No. 431-1 at PageID #22579.) Again, at least some history about Defendants and how the Ventralight ST, including the ST hydrogel coating, came to market and to be implanted in Plaintiff is relevant and not unduly prejudicial. *Old Chief*, 519 U.S. at 189; *In re Davol, Inc./ C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2021 WL 486425, at *7 (S.D. Ohio Feb. 10, 2021). But it bears reiterating that too much evidence about the history of the Ventralight ST will unduly delay and waste time at trial.

At the same time, evidence about how Defendants molded the market for other devices is inadmissible. This is propensity evidence forbidden by Federal Rule of Evidence 404(b). By pointing to Defendants' alleged prior instances of "molding the market," Plaintiff seeks to induce the jury to conclude that Defendants did the same for the Ventralight ST. *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2020 WL 7767625, at *3 (S.D. Ohio Dec. 30, 2020). And although Plaintiff countered at oral argument that this evidence is admissible as evidence of motive, a permissible purpose under Rule 404(b)(2), evidence of Defendants' motive must be at issue. *United States v. Hazelwood*, 979 F.3d 398, 411 (6th Cir. 2020) (quoting *United States v. LaVictor*, 848 F.3d 428, 445–46 (6th Cir. 2017)); *see also In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, --- F. Supp. 3d ----, Nos. 2:18-md-2846, 2:18-cv-01509, 2021 WL 81821, at *3 (S.D. Ohio Jan. 11, 2021) (discussing in greater detail the framework for a Rule 404(b) analysis). At this point, Plaintiff has not established that motive is a triable issue. Accordingly, the part of this motion in limine addressing other devices is provisionally granted.

One of the exhibits is also evidence that Defendants violated the applicable standard of care. Under Utah law, the standard of care is partially defined by federal regulatory standards. *In re Davol, Inc./C.R. Bard, Inc.*, 2020 WL 6603657, at *7. Plaintiff argues that certain exhibits show Defendants "position[ed] ST as anti-adhesion (when it was not permitted to do so by the FDA)." (ECF No. 431-1 at PageID #22577–78, 22580–81.) This includes exhibits ECF Nos. 368-23, -38, -39, and -40. Defendants dispute that this is evidence of any violation of FDA regulations because the FDA and Defendants agreed on appropriate wording in 2010. (ECF No. 373 at PageID #20240.) But Exhibit ECF No. 368-40, a presentation to the National Hernia Society, is relevant to whether Defendants complied with FDA regulations. The exhibit is from 2014, suggesting that

an anti-adhesions representation would go against the agreement that Defendants reached with the FDA. (ECF No. 368-40 at PageID #19840.) The remaining exhibits bear no connection to the facts of this case. Exhibits ECF Nos. 368-23 and -38 are from 2007 and 2008, well before the events in this case. Thus, they are not evidence that Defendants made these representations in contravention of FDA regulations when Plaintiff had his Ventralight ST implanted. At best, this is character evidence, suggesting that prior non-compliance with FDA regulations is evidence of non-compliance with FDA regulations for the time period in this case. *See* Fed. R. Evid. 404(b). Exhibit ECF No. 368-39 has no date, and so the Court cannot discern whether it is relevant.

Plaintiff also argues that the exhibits in this category are admissible to show that Defendants influenced the medical standard of care. (ECF No. 368 at PageID #18946.) Because the standard of care for medical doctors is beyond the ken of the average jury, expert testimony is required that shows that the doctor breached the standard of care. *Ruiz v. Killebrew*, 459 P.3d 1005, 1009 (Utah 2020). These exhibits thus are inadmissible to define the medical standard of care. Plaintiff cites no authority to the contrary. (ECF No. 368 at PageID #18946.)

Plaintiff points to previous decision in this case, arguing that the Court has admitted similar evidence of the medical standard of care (ECF No. 431-1 at PageID #22577), but this misrepresents the Court's previous decisions. The Court determined that Defendants "may use the term 'medical standard of care,' and not to refer to the 'standard of care,' as that is a different determination." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, Nos. 2:18-cv-01509, 2:18-md-2846, 2020 WL 6605648, at *2 (S.D. Ohio Sept. 11, 2020). In a later decision, the Court elaborated that the "medical standard of care" refers to Plaintiff's implanting surgeon's conduct but the "standard of care" refers to the standard of care that will determine whether

Defendants were negligent. (ECF No. 345 at PageID #1860.) These decisions address the use of terminology and no more.

C. Category 3: Evidence of Defendants' conduct supporting an award of punitive damages

The next category that Plaintiff designated is "[e]vidence probative of 'reckless indifference,' 'knowing and reckless indifference,' financial motive and/or reason for acquiring ST in light of Defendants' knowledge and prior admissions related to the ST efficacy/resorption issue," which goes to the issue of punitive damages. (ECF No. 431 at 22573.) Defendants again argue that these documents are irrelevant to whether Defendants adequately warned Dr. Jensen because this is not a marketing document, and the Court agrees. (*E.g.*, ECF No. 433-1 at PageID #22597.) Nevertheless, all but one of the exhibits in this category is relevant to the punitive damages issue, though the Court remains mindful of Rule 403 concerns.

Plaintiff points to five relevant exhibits in this category: a 2008 Sepramesh IP presentation (ECF No. 368-21), the Zebra deal presentation (ECF No. 368-23), a 2007 presentation titled "Davol 3 Year Plan: 2008 – 2010 (ECF No. 368-24), a PowerPoint presentation on Sepra Sales (ECF No. 368-27), and a letter to customers regarding a non-profit public watchdog group called Public Citizen's petition to the FDA for withdrawn approval of Seprafilm (ECF No. 368-29). Plaintiff argues that these exhibits show that prior to acquiring the license to the Sepra Technology through the Zebra deal, Defendants attacked the resorption period claims of the hydrogel barrier technology in Sepramesh IP, and that after acquiring the license, Defendant marketed the Ventralight ST despite indications that the resorbable barrier did not work as Defendants claimed. This goes directly to the nature of Defendants' conduct.[4]

[4] Defendants point to *Txo Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 460 (1993), arguing that these exhibits must bear some sort of connection to Defendants' conduct and the harm that has occurred to justify punitive damages. (*E.g.*, ECF No. 433-1 at PageID #22598.) This is accurate, but the Supreme Court in *Txo* focused

The exhibit of the 2003 "Marketing and Product Development Presentation, however, is irrelevant to the availability of punitive damages. Plaintiff argues that the exhibit shows that Defendants had been considering acquiring the ST license from Genzyme from 2003 (ECF No. 368 at PageID #18945), but this says nothing of Defendants' knowledge about the efficacy of the ST hydrogel technology or the nature of Defendants' conduct in relation to Plaintiff and his injuries. (ECF No. 368-22 at PageID #19379.)

The Court has significant Rule 403 concerns. The relevant exhibits voluminously address other devices and marketing strategies that are entirely unrelated to the Ventralight ST. Additionally, these exhibits appear to explain to sales employees general business strategies — increase the market share to drive out competition and drive up profits. Accordingly, the probative value of the exhibits in showing Defendants' willful, reckless, or intentionally fraudulent behavior could be quickly be outweighed by concerns of unduly prolonging trial. These are matters best left for trial.

D. Category 4: Evidence showing Defendants' knowledge and conduct related to the ST coating

Next, Plaintiff's fourth category: "Admission as to both general causation and liability; relevant to show notice/scienter relating to the ST efficacy/resorption warnings issue." (ECF No. 431 at 22573.) In other words, Plaintiff claims that these exhibits demonstrate that Defendants either admitted or did not disclose that the ST coating or its predecessors resorbed within seven, not twenty-eight, days. Defendants argue that these documents are not responsive, *i.e.* not marketing documents (*E.g.*, ECF No. 433-1 at PageID #22599–60), and again, the Court agrees. However, some of these exhibits are otherwise relevant.

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on the punitive damage award and not specific exhibits that support that may eventually support an award. 509 U.S. at 460.

These exhibits fall within two groups: those in which Defendants admit or do not disclose that Sepramesh IP resorbs within seven days, not twenty-eight days, (ECF Nos. 368-15, -19, -20, -21, -27, -28) and those in which Defendants attack Sepramesh (ECF Nos. 368-12, -13, -14, -16). The first group of exhibits is relevant because Sepramesh IP is a predicate device to Sepra Technology. Defendants' statements that they were aware of the shorter resorption window and presentations of Sepramesh IP alongside other resorbable devices within twenty-eight days is relevant to Defendants' knowledge and the reasonableness of Defendants' conduct. The exhibits from the second category are not relevant. All address Sepramesh, not Sepramesh IP, and Sepramesh is not a predicate device to the Ventralight ST. (ECF No. 437 at PageID #22659–60.) [5] Moreover, three of the four exhibits do not discuss the resorption period of the ST coating; they only merely state that the ST coating is not a permanent barrier. (ECF Nos. 368-12, -13, -14.)

As before, Plaintiff's exhibits encompass other devices and topics, too. For this reason, the admission of many of these exhibits in full runs the risk of confusing the jury, delaying trial, etc. as forbidden by Rule 403.

E. Category 5: Notice of user need for ST coating to last at least twenty-eight days

Plaintiff describes the fifth category of exhibits as those demonstrating Defendants' "[n]otice as to 'user needs' for resorption barrier =≥28 days." (ECF No. 431 at 22573.) Again, Defendants assert that these non-marketing documents are not responsive to their initial motion. (*e.g.*, ECF No. 433-1 at PageID #22614.) The Court agrees, but all exhibits are relevant to this case as evidence of Defendants' notice as to whether they should have designed the Ventralight ST with a 28-day resorption window and if they in fact did.

[5] Seprafilm received premarket approval from the FDA, and then Seprafilm was the predicate device for Sepramesh's 510(k) application, and Sepramesh was the predicate device for Sepramesh IP's 510(k) application. (ECF No. 437 at PageID #22659–60.) Defendants acquired the license for from Genzyme before Defendants submitted the Sepramesh IP's application. (*Id.* at PageID #22660.)

The exhibits are relevant because they show that Defendants were aware of the need for a 28-day long resorption window and that the Ventralight ST was not designed to satisfy this user need. Three of these exhibits address other devices that are not predicates to the Ventralight ST, but still indicate that the user need for a resorbable barrier is about a month. (ECF Nos. 368-14 at PageID #19123 (Sepramesh); 368-41 at PageID #19906 (Composix E/X); 368-42 at PageID #19961 (Ventrio).) Another exhibit is a version of the Ventralight ST product specification sheet that shows that the Ventralight ST was designed with a seven-day resorption window to minimize adhesions, not a 28-day window. (ECF No. 368-43 at PageID #20079.) The last exhibit is another version of the Ventralight ST product specification sheet that shows no span of time was indicated to minimize adhesions. (ECF No. 368-44 at PageID #20091.)

Again, however, many of these exhibits span dozens of pages that address more than Defendants' notice and knowledge that a 28-day window for resorption was the appropriate user need. For example, ECF No. 368-42 contains 155 pages—only one of which is relevant to Defendants' knowledge. For this reason, Rule 403 concerns are imminent should Plaintiff attempt to admit more than the necessary documentation to establish foundation and other preliminary admissibility issues.

F. Category 6: Undisputed marketing materials

Finally, the exhibits in Plaintiff's last category—"[d]ocument[s] seen or likely to be seen by Dr. Jensen" (ECF No. 431 at PageID #22573—are not exhibits that Defendant seek to exclude as non-responsive to their initial motion in limine. (ECF No. ECF No. 433-1 at PageID #22610–11.) This includes two documents, ECF Nos. 368-8 and 368-9, and Defendants have no other evidentiary objections. (ECF No. 375 at PageID #20317.)

IV. Conclusion

For the reasons set forth above, Defendants' Motion in Limine No. 15 (ECF No. 218) is **GRANTED IN PART AND DENIED IN PART**.

IT IS SO ORDERED.

6/28/2021
DATE

s/ Edmund A Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE